West Yorkshire Health and Care Partnership

West Yorkshire

Commissioning Policy

Treatment	Melatonin
For the treatment of	Treatment of disorders specified in the commissioning position below.
Important notes	**The limited evidence base for melatonin only demonstrates increases to total sleep duration to around 30 minutes or less (see evidence below).** **When melatonin is deemed necessary by the specialist, it is initiated in specialist services. Patients will receive prescriptions for supplies of medication from the specialist service until the drug has been stabilised (time allowed for common side-effects to have occurred) AND deemed to be effective AND dose titration has been completed AND amber agreement has been established with the primary care prescriber, but it can be continued by the specialist service when appropriate.** **Not recommended for initiation in primary care.**
Commissioning position	West Yorkshire Health and Care Partnership only supports the use of melatonin when used: 1. for sleep onset insomnia and delayed sleep phase syndrome in children and young people 2 to 18 years with conditions such as Autism Spectrum Disorder (ASD), Smith-Magenis syndrome, cerebral palsy (up to the age of 25) or learning disability (LD); • **and** standard non-pharmacological behavioural modification methods have failed (sleep hygiene/behavioural measures); • **and** other medical causes of sleep disturbance such as sleep apnoea, have been excluded; • **and** sleep problems are adversely affecting quality of life and have lasted for at least 6 months or sleep disturbance is so severe that it is causing significant family disturbance (such as affecting people's ability to care for the family); • **and** disrupted sleep disturbance has been documented via sleep diaries for at least 4 weeks; • **and** patients have been assessed by a specialist Child and Adolescent Mental Health Services (CAMHS) doctor,

	paediatric doctor with expertise in sleep management or paediatric LD doctor; • **and** patients have regular treatment reviews scheduled into their clinical notes; • **and** treatment is stopped within the recommended treatment intervals for safety reasons (see Safety section). • If treatment has been assessed as needing to be continued such patients can be transitioned to adult services when the time comes. This needs to be planned and transfer of care accepted before the person reaches 18. If patient was on a liquid formulation, consider if a tablet or crushed tablet is now appropriate. 2. in patients over 18 years for rapid eye movement (REM) sleep disorders associated with Parkinson's disease • **and** clonazepam is contra-indicated, ineffective or not tolerated; • **and** pharmacological causes have been addressed; • **and** melatonin has been initiated by a neurologist. 3. for adults with parasomnias, including delayed sleep phase syndrome; • **and** melatonin has been initiated by a specialist respiratory consultant • **and** standard non-pharmacological behavioural modification methods have failed (sleep hygiene/ behavioural measures); 4. to prevent cluster headache in adult patients when tried as a third line option after other treatments with an improved evidence base have been found to be ineffective; • **and** melatonin has been initiated by a neurology specialist; 5. for indications approved by committees in secondary and tertiary care for **inpatient use**. Patients currently prescribed melatonin who are not covered by indications approved in the commissioning statement can continue until they and their NHS clinician consider it appropriate to stop. West Yorkshire Health and Care Partnership **does not** recommend melatonin for: • ADHD if patient does not have a concomitant diagnosis of ASD; • sleep disturbances linked to shift work; • adults with primary insomnia;

	• Chronic Fatigue Syndrome (CFS)/Myalgic Encephalomyelitis (ME); • Alzheimer's disease; • any other non-formulary indication. Do **NOT** prescribe melatonin on the NHS for jet lag. See Appendix 1 for further information, including duration of treatment. See Appendix 2 for how to crush melatonin tablets.
Contact for this policy	West Yorkshire ICB Medicines Optimisation Steering Group

Appendix 1

Indication	Neurological or behavioural disorders including ASD without ADHD; emotional dysregulation; chronic sleep-onset insomnia in patients 2-18 years	Patients 2 - 18 years with Smith-Magenis syndrome	ADHD with concomitant ASD in patients 2 - 18 years	In patients 2-18 years: neurodevelopment disorder including delayed brain maturation; sensory dysfunction especially visual; dysfunction of sleep centres; cerebral palsy (up to the age of 25)	REM sleep disorder in patients ≥18 with Parkinson's disease	Parasomnias including delayed sleep phase syndrome in patients ≥18	Cluster headache in patients ≥ 18 when 1st, 2nd and 3rd line preventative licensed options have not been effective
First line	Sleep diary. Non-pharmaceutical treatment including behavioural therapy and sleep hygiene for a minimum of 2 months (e.g fixed bedtime, even at weekend or on holiday; minimise screen-time before bed). Non-pharmaceutical treatments need to be continued if	Sleep diary. Behaviour management and sleep hygiene. These modifications need to be continued if melatonin is started	Sleep diary. Non-pharmaceutical treatment including behavioural therapy and sleep hygiene for a minimum of 2 months (e.g fixed bedtime, even at weekend or on holiday; minimise screen-time before bed).	Sleep diary. Non-pharmaceutical treatment including behavioural therapy and sleep hygiene for a minimum of 2 months (e.g fixed bedtime, even at weekend or on holiday; minimise screen-time before bed). Non-pharmaceutical treatments need to be continued if	Address possible pharmacological causes. Clonazepam	Reduce triggers such as caffeine, alcohol, noise. Ensure there is a stable and adequate sleep-wake schedule. These modifications need to be continued if melatonin is started	Nerve block. Verapamil

	melatonin is started		Non-pharmaceutical treatments need to be continued if melatonin is started	melatonin is started			
Specialist	Consider melatonin as an option. Assess each patient to see if they are likely to be able to take tablets or crushed tablets or if another option is necessary. Start melatonin if deemed necessary. Explain to the patient/parent/carer that duration of treatment is a maximum of 2 years (except cluster headache). Explain how to crush tablets and give them an information leaflet. Dose titration to be completed by the specialist						
Which specialist?	CAMHS doctor or paediatric doctor with expertise in sleep management	CAMHS doctor or paediatric doctor with expertise in sleep management	CAMHS doctor or paediatric doctor with expertise in sleep management	CAMHS doctor or paediatric doctor with expertise in sleep management	Neurologist	Specialist respiratory consultant	Neurology specialist
All patients	Clinician starting melatonin to schedule regular reviews in patient's clinical notes for patient to return to the service. If prescribing a liquid for a child, check if they can be transferred onto tablets/crushed	Clinician starting melatonin to schedule regular reviews in patient's clinical notes for patient to return to the service. If prescribing a liquid for a child, check if	Clinician starting melatonin to schedule regular reviews in patient's clinical notes for patient to return to the service. If prescribing a liquid for a child, check if	Clinician starting melatonin to schedule regular reviews in patient's clinical notes for patient to return to the service. If prescribing a liquid for a child, check if they can be transferred onto tablets/crushed tablets as they get older	Clinician starting melatonin to schedule regular reviews in patient's clinical notes for patient to return to the service	Clinician starting melatonin to schedule regular reviews in patient's clinical notes for patient to return to the service	Initial monitoring in specialist service

	tablets as they get older	they can be transferred onto tablets/ crushed tablets as they get older	they can be transferred onto tablets/ crushed tablets as they get older				
Duration	Review patients for continued need and effectiveness after the first 3 months and stop if ineffective or no longer necessary. Review continued treatment every 6 months for up to 2 years. Specialist to consider the need for a drug-free holiday lasting 2 to 4 weeks every 6 to 12 months	Review in first 3 months. If no response, stop. If continue, review treatment every 6 months. Slenyto is licensed for up to 2 year's treatment	Review in first 3 months. If no response, stop. If continue, review treatment every 6 months. Slenyto is licensed for up to 2 year's treatment	Review patients for continued need and effectiveness after the first 3 months and stop if ineffective or no longer necessary. Review continued treatment every 6 months for up to 2 years. Specialist to consider the need for a drug-free holiday lasting 2 to 4 weeks every 6 to 12 months	Review patients for continued need and effectiveness after the first 3 months and stop if ineffective or no longer necessary. Review continued treatment every 6 months for up to 2 years. Specialist to consider the need for a drug-free holiday lasting 2 to 4 weeks every 6 to 12 months	Review patients for continued need and effectiveness after the first 3 months and stop if ineffective or no longer necessary. Review continued treatment every 6 months for up to 2 years. Specialist to consider the need for a drug-free holiday lasting 2 to 4 weeks every 6 to 12 months	Indefinite

Formulations	**Tablet formulations:** Many children can be trained to swallow tablets and prescribers and dispensers should encourage this important life skill. The website KidzMed has some resources to help with this [1]. In addition, Medicines for Children's website describes how to give tablets to children and Leeds Trust has a patient leaflet which includes techniques on how to swallow tablets. A patient information leaflet on how to crush melatonin tablets is available in appendix 2. Melatonin PR 2mg tablets are **first line** (off-label) except for patients with ASD and/or Smith-Magenis syndrome. Patients should swallow them whole for a prolonged effect. For patients with swallowing difficulties melatonin PR 2mg tablets can be halved or divided into four to maintain the prolonged release effect to some extent. For an immediate release effect and for patients with swallowing difficulties, take crushed and mixed with 15-30ml water, orange juice or milk or soft food for example jam or yoghurt (off-label). Slenyto PR tablets 1 or 5mg are licensed for children with ASD and/or Smith Magenis syndrome. For a prolonged effect, patients should swallow them whole. Whole tablets can be put into soft food such as yoghurt, ice cream or into orange juice. Some patients with swallowing difficulties will be able to take the dose in this manner. For an immediate release effect and if patient with swallowing difficulties has failed on tablets in soft food, Slenyto can be halved, quartered or crushed (off-label). Explain carefully to patients or carers how to crush tablets and given them an information leaflet (Appendix 2). Advise that if tablets are mixed with fluid or food, they must be taken immediately. **Liquid formulations:** Liquid forms of melatonin are **not** recommended. If there is **no** other option, then weigh up the information given below. As a prescriber who is considering a liquid formulation be aware that: • excipients in the formulation may be particularly problematic in children; • the same product may not be dispensed each time, which may have implications for children with ASD, for example; • the patient information leaflet may be confusing for patients/parents/carers, for example it may say do not give the product to children;

	• some products have a short shelf-life once opened so waste is possible. Take into consideration the patient's weight and other medication. Give the patient/parent/carer sufficient information to allow them to make an informed decision about the medicine. Excipients in liquids include propylene glycol, sorbitol and ethanol (alcohol). The total daily dose of excipients needs be calculated and checked by the initiating prescriber to ensure they are within the safety limits for the age and weight of the patient. Particular care should be exercised in children aged 5 years and under and patients on more than one medication. <u>Propylene glycol maximum daily safety limit [2]:</u> 1 month – 4 years: 50mg/kg 5 years – 17 years: 500mg/kg For example, melatonin doses greater than 5.3mg in a 2 year old weighing 16kg or 7.65mg in a 4 year old weighing 23kg would exceed safety limits. <u>Sorbitol maximum daily safety limit:</u> all ages of patients - greater than 140mg/kg/day may cause a laxative effect and gastrointestinal discomfort. Sorbitol may also affect the bioavailability of other medicinal products administered concomitantly [3]. Ethanol (alcohol) is included in some medicines as a preservative or solvent. Long-term exposure to even low levels of ethanol in medicines on the health and development of children has not been evaluated. It can cause interactions with other medicines or have a central nervous system depressant effect [4]. Patients or carers may feel that a medicine containing alcohol is inappropriate for religious or cultural reasons. Healthcare professionals need to be sensitive to these beliefs [5]. Before prescribing, make patients or carers aware of excipients the product contains (for example, propylene glycol, sorbitol, sugar, alcohol) and if the product has a short shelf-life once opened. Melatonin 1mg/ml oral solution (Colonis) contains propylene glycol and sorbitol. It can be considered for: • patients who require medication to be administered via a fine-bore feeding tube; • children over 5 years.

	Exceptions are very light children or children on other liquid preparations which contain excipients of concern and in total would be above safety limits. As Colonis liquid is licensed, the calculations of excipients are easy to do. Licensed products used off-label are higher up the MHRA's hierarchy of medicines than unlicensed ones [6]. Due to concerns raised above, the product of last resort is melatonin 1mg/1ml unlicensed special. If it is ordered and dispensed as this particular product, then the same formulation can be guaranteed each time. In addition, the excipients will be known, and the prescriber can easily access knowledge within the pharmacy department. Try to avoid high doses in young children as it contains a small amount of propylene glycol (less than 9% v/v). Further information on choosing a liquid medication for children is available from the Royal College of Paediatrics and Child Health/Neonatal and Paediatric Pharmacists Group. Information on crushing tablets for enteral tubes is available from specialist centres (such as Evelina London) and NEWT.

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Appendix 2

Melatonin tablets - advice for crushing

If you have been given a prescription for melatonin tablets and been asked to crush them prior to taking them the following advice may be useful.

Melatonin prolonged-release 2mg tablets (also called Circadin®)

Prepare the tablet as follows:

1. Crush the tablet with a tablet crusher, or between two metal spoons.
2. Add the powder to 15-30mL of water, orange juice, milk or soft food such as jam or yoghurt, and mix well.
3. If mixed with liquid, draw up the solution into an oral syringe. If mixed with food, place on a spoon.
4. Administer the dose to the patient.
5. If used, rinse out tablet crusher with water and administer this also.

Melatonin prolonged-release 1mg or 5mg tablets (also called Slenyto®)

Prepare the tablet as follows:

1. Crush the tablet with a tablet crusher, or between two metal spoons.
2. Add the powder to 15-30mL of orange juice or yoghurt, and mix well.
3. If mixed with juice, draw up the solution into an oral syringe. If mixed with yogurt, place on a spoon.
4. Administer the dose to the patient.
5. If used, rinse out tablet crusher with water and administer this also.

- Don’t crush tablets in plastic containers, other than commercially available tablet crushers, as the medicine may stick to the plastic.
- Don’t use boiling water to dissolve tablets as it may affect the way the medicine works.
- Don’t leave oral medicines unattended in syringes.
- Don’t administer any medicine that you have not prepared yourself.

Tablet crushers can be purchased from your local community pharmacy, for a few pounds. They are reusable and can be washed and dried after use. If using two metal spoons, select two spoons of similar size sitting one spoon inside the one below. Make a small gap between the spoons, and place one tablet between these surfaces and gently squeeze the spoons together. The tablet should break up without shooting out. Further crushing will make a finer powder. Please note that it is not necessary to crush to a very fine powder, as once the tablet is roughly crushed, it will offer “immediate release” characteristics as desired. Repeat if more than one tablet is required to provide the dose.

There are no safety concerns with crushing these tablets, however it will affect the prolonged-release properties of the product. The tablet keeps its prolonged-release properties as long as it is swallowed whole. The prolonged-release properties will be maintained to some extent if the tablet is halved or divided into 4 quarters. If it is crushed it will release melatonin similarly to an immediate release formulation.

If you have any queries, please speak with the person who prescribed your medicine, your community pharmacist, the pharmacist at your practice, or your GP.

Background information	Melatonin is a hormone secreted by the pineal gland which has an important role in the regulation of circadian rhythm [7]. Before prescribing melatonin to appropriate patients the service needs to consider social prescribing to deliver the behavioural interventions as part of universal personalised care [8,9]. Insomnia occurs in about 1 to 6% of the general paediatric population [10]. Sleep disorders associated with ASD may affect 30 to 53% of children and young people [11]. In children with neurodevelopmental or psychiatric comorbidities it is as high as 50 to 75% [10]. Sleep disturbance may include delayed onset of sleep, frequent waking, and early morning waking or day-night reversal of sleep pattern [12]. These can have an impact on physical and mental health, social, academic and cognitive functioning [13]. Children may grow out of their delayed sleep onset [14]. Sleep disturbance in patients with Parkinson's disease may be caused by degeneration of sleep regulation centres; restless leg syndrome and depression, for example. REM sleep behaviour disorder associated with Parkinson's is characterised by disruptive behaviours, such as shouting, kicking or punching [15]. Parasomnias are unusual behaviours occurring during sleep which disturb the patient/bed partner/family members. They include sleep paralysis and REM sleep behaviour disorder [16]. Support for everyone to get a good night's sleep is available from The Sleep Charity [17].
Summary of evidence/ rationale	**Neurological and developmental disorders** In the MENDS trial children with a wide range of neurological and developmental disorders were randomised to immediate release melatonin (70 patients) or placebo (76 patients). The primary outcome was total night-time sleep time calculated using sleep diaries at 12 weeks compared with baseline. The difference in night-time sleep time between the melatonin and placebo groups adjusted for baseline was 22.43 minutes (based on results from 110 children). This difference was not clinically worthwhile as it was less than the minimum clinically effective difference specified at the outset of the trial [18]. **ASD or Smith-Magenis syndrome** SIGN guidance on patients with ASD who have sleep difficulties which have not resolved following behavioural interventions suggests that a trial of melatonin could be considered in conjunction with behavioural interventions [19].

	The Scottish Medicines Consortium (SMC) does not recommend Slenyto® for the treatment of insomnia in children and adolescents with ASD and/or Smith-Magenis syndrome**.** The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and the company did not present a sufficiently robust clinical and economic analysis to gain acceptance for use in Scotland [20]. The All Wales Medicines Strategy Group's (AWMSG) review of Slenyto concluded that the drug is recommended as an option for use within NHS Wales for the treatment of insomnia in patients aged 2 to 18 years with ASD and/or Smith Magenis syndrome, where sleep hygiene measures have been insufficient [21]. The pivotal trial for licensing of Slenyto included 121 children with ASD and only 4 patients with Smith-Magenis syndrome. The children were aged 2 to 17 years. 25.6% had a concomitant diagnosis of ASD and 28.8% of ADHD. The European Medicines Agency notes that it is hard to draw any specific conclusions from the results of this study on efficacy of melatonin in rare neurogenetic syndromes such as Smith-Magenis syndrome [10]. In the trial the double-blind part lasted 13 weeks. Patients could then enter a 13-week open-label study and then a 78 week follow-up and run-out period. The primary end point, assessed at 13 weeks, was total sleep time. This was improved in the Slenyto group by 51.16 minutes and 18.73 minutes in the placebo group (estimated treatment difference of 32.43 minutes). The secondary end point of sleep latency was improved by Slenyto by 25.30 minutes compared to placebo. However, not all the other endpoints, including number of awakenings and various other assessments scales on daytime function of the children and caregivers' sleep, were positively affected by melatonin [10]. **ADHD** PrescQIPP does not recommend melatonin for sleep disorders associated with attention deficit hyperactivity disorder (ADHD) unless the child or young person has a concomitant diagnosis of ASD [11]. Although melatonin was included in the scope for NICE's guideline on ADHD, there was insufficient evidence to make a recommendation [22,23]. The ADHD guideline says in the sleep section, use something like a sleep diary to monitor changes in sleep pattern and adjust medication accordingly [24]. This is because common medicines for ADHD can cause disturbances of sleep [25]. Stopping unlicensed melatonin led to relapse of sleep onset insomnia in most cases when it was used for more than 30 days [26]

	A study of 105 children (aged 6 to 12 years) was undertaken in the Netherlands [27]. It should be noted that diagnostic criteria may not be the same as in the UK. All the patients in the study were offered open-label melatonin in a follow-on study [28]. The mean follow-up time was 3.7 years (94 patients). This study has been used to obtain a licence for the Adaflex® melatonin brand. A small Canadian study was undertaken on 19 patients aged 6 to 14 years [29]. The cross-over design limited the effects of between-patient variability in sleep patterns. Another limitation was that the sleep hygiene intervention lasted only 10 nights prior to the treatment phase. There is no good quality evidence for the use of Circadin® in children with ADHD. Small studies used unlicensed melatonin in daily doses of 3 to 6mg [26]. Limitations of these studies include small number of participants, missing data, exclusion of children on stimulant medicines for ADHD, subjective measure of effectiveness (opinion of parents) and in one study it was unclear if allocation was concealed. These limited studies suggest that unlicensed melatonin for 10 days to 4 weeks may improve the time taken to fall asleep by approximately 20 minutes. Sleep duration appeared to be improved by about 15 to 20 minutes. Longer term efficacy is unclear. Any reported benefits in patients with ADHD have not been associated with improvements in ADHD symptoms, behaviour, cognition or quality of life. Stopping melatonin led to relapse of insomnia in most treated patients [26]. The MENDS and Dutch trials mentioned above were included in a published meta-analysis of neurodevelopment and developmental conditions. Although the results suggested that melatonin improved total sleep time and sleep onset latency the authors concluded that their findings were limited by the heterogeneity and small sample sizes of the included studies [30]. A clinical trial has looked at melatonin, cognitive behavioural therapy (CBT) or both in children with ASD. Results were available for 134 patients who completed the 12-week trial. Melatonin with CBT was the most effective modality at reducing insomnia symptoms including total sleep time and sleep onset latency [31]. **Cerebral palsy** The NICE guideline for cerebral palsy in under 25s says that if no treatable cause is found for sleep disturbances, consider a trial of melatonin, particularly for problems with falling asleep [32].

	Shift work NICE CKS does not recommend the use of melatonin in primary care for problems with sleep due to shift work as there is limited and conflicting evidence of benefit [33]. **Parkinson's disease** Treatment with clonazepam can be considered with melatonin as a second-line option if possible pharmacological causes have been excluded [15]. **Alzheimer's disease** NICE guideline NG97 states that melatonin should not be offered for patients living with Alzheimer's disease who have insomnia. Instead offer a personalised approach which includes exposure to daylight, exercise and sleep hygiene education [34]. A Cochrane Review found four trials of melatonin for patients with dementia due to Alzheimer's disease. They showed that melatonin did not improve sleep in this group of patients [35]. Trazodone or low-dose mirtazapine have been shown to have modest efficacy in patients with Alzheimer's disease [36] following sleep hygiene approaches or other non-medical therapies [37,38]. **Parasomnias** The British Association for Psychopharmacology has published a consensus statement on insomnia, parasomnias and circadian rhythm disorders [16]. Drug treatment decisions are based on severity and frequency of events. Parasomnias which cause significant distress can be treated with melatonin. **Cluster headache** The British Association for the Study of Headache's guideline for adults recommends nerve block or verapamil for preventing cluster headache. Melatonin is included in the table of other preventative treatments [39]. This is based on a very small pilot study where melatonin was found to be more effective than placebo at reducing headache frequency [40]. **CFS/ME** A NICE clinical guideline says that melatonin may be considered for children and young people with chronic fatigue syndrome/ myalgic encephalomyelitis who have sleep difficulties [41]. However, this seems to be based on expert consensus rather than robust

clinical trials [42]. One trial of 30 patients found no effect of melatonin [43].

Primary insomnia in adults

The evidence for Circadin comes from three randomised trials with very subjective outcomes. Melatonin shortened sleep latency times by 9 and 15 minutes compared to placebo. The trials did not show a benefit on total sleep time. MTRAC gave Circadin a low place in therapy as there were no comparisons with other treatments for insomnia [44].

The manufacturer of Circadin did not make a submission to the SMC so the drug is not recommended in Scotland for the short-term treatment of primary insomnia in patients aged 55 and over [45]. Circadin was excluded from appraisal by AWMSG [46].

A PrescQIPP review of hypnotics and anxiolytics ends with a summary that states that Circadin may appear to be an option for sleep when there is a concern over dependence, but the EMA noted that the treatment effect was small, and it is more expensive than other hypnotics [46]. In line with NICE TA77, because of the lack of compelling evidence to distinguish between Z-drugs or the shorter-acting benzodiazepine hypnotics, the drug with the lowest purchase cost should be prescribed [48].

Sleep disorders in adults who are totally blind

A NICE evidence review found one randomised trial of 13 people and two cross-over studies (subject to potential bias) of a total of 17 adults who were totally blind. These were underpowered to show a difference between melatonin and placebo [23]. A total of 16 further studies were excluded from the summary [49].

Jet lag

Melatonin must not be prescribed for jet lag on NHS prescription as GPs are not responsible for providing NHS treatment of conditions which may occur while travelling or abroad [50].

Safety:

In the MENDS study there were no significant differences between the two groups in terms of the reporting of adverse events [18].

Unlicensed melatonin appeared to be well tolerated in the short to medium term. Transient mild to moderate adverse effects included headache, nausea, drowsiness and dizziness [26]. In adult clinical

	trials, Circadin was associated with headache, nasopharyngitis, back pain and arthralgia [51]. The licensed products are designed for short term use. Data are available for adults treated with melatonin prolonged release (PR) 2mg for up to 13 weeks and two years in children treated with Slenyto [51,52,53,54]. The European Medicines Agency (EMA) notes that there is a need for further long-term safety data, especially related to uncertainty of the effects of exogenous melatonin on endocrine and pubertal development [10]. Long-term use of melatonin may delay children's sexual maturation, possibly by disrupting the decline in nocturnal melatonin levels that occurs at the onset of puberty [11]. The risks associated with the long-term use of benzodiazepine and Z-drugs are well known and include cognitive impairment, falls, confusion, dependence and withdrawal symptoms. Discuss the risks of melatonin treatment in the elderly. These include falls and fractures. Therefore, only use hypnotics if insomnia is severe causing significant distress or not likely to resolve soon, using the lowest dose that controls symptoms for the shortest period of time [55]. It is known that metabolism of melatonin declines with age [51]. STOMP (stopping over medication of people with a LD, autism or both) is a national project to stop over medication with psychotropic medicines of people with a LD, autism or both. It includes encouraging people to have regular check-ups about their medication; healthcare professionals involve people, families and carers in decisions about medicines; and thinking about non-drug therapies and practical support so people are less likely to need as much medication, if any [56].
Cost/ resource impact:	Approximately £2.5m is spent per year on melatonin in primary care across West Yorkshire. Particularly due to specials and liquids, the cost per prescription item is higher for children than adults.

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